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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,971	02/02/2001	John D. Shaughnessy	D6138	3345

7590
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11/04/2003

EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 11/04/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/778,971

Applicant(s)

SHAUGHNESSY, JOHN D.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 9-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. The amendment filed 8/11/2003 (paper no. 9) is acknowledged and entered into the record. No claims have been canceled or added.
2. Claims 1-21 are pending, claims 9-21 are withdrawn from further consideration as being drawn to a non-elected subject matter.
3. Claims 1-8 are examined on the merits.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

4. The rejection of claims 2-4 under 35 USC 112, 1st paragraph for lacking proper written description is maintained for the reasons of record. The rejection is *withdrawn* for claim 1. Applicant argues that the disclosure of SEQ ID No: 1 is adequate disclosure to be enabled for the full scope of fragments derived from SEQ ID No: 1. Applicant's arguments have been carefully considered but are not found persuasive. In order to satisfy the requirements for written description, the specification must disclose to one of skill in the arts that the applicant was in possession of the claimed invention at the time the invention was made, or disclose a representative number of species so as to be entitled to the broad scope of "fragments" claimed. The instant specification has only disclosed the sequence of SEQ ID No: 1 and is therefore not commensurate in scope to fragments that include 10 contiguous amino acids to the full-length sequence of SEQ ID No: 1. There are hundreds if not thousands of possible fragments that are found within SEQ ID No: 1, and one of skill in the art would not be able to determine if the applicant was in possession of *all* these fragments. Furthermore, given the lack of a functional activity associated with the fragments, one of skill in the art would not be able

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to readily test or screen for such fragments claimed. The amendments to the claims do not overcome the rejection of record because the claim limitations recites fragments of which do not have any particular amino acid sequence except that being derived from SEQ ID No: 1.

Claim Rejections Maintained - 35 USC § 101

5. The rejection of claims 1-8 under 35 USC 101 as lacking a substantial utility is maintained for the reasons of record. Applicant's argues that the novel gene, *Evi27*, is a member of the IL-17 receptor (IL-17R) family, based on its sequence homology to the human and mouse IL-17 receptor. Applicant further argues that based on its homology to the human and mouse IL-17R, *Evi27* may act as a receptor for IL-17B and IL-17C cytokines and thus would ultimately have therapeutic utility. Applicant further states that the courts have found that structural similarity of know compounds that have utility can be supportive of an asserted utility to a novel compound. Applicant's arguments have been carefully considered but are not found persuasive. The guidelines for establishing whether a molecules has complied with the utility requirement, the specification must provide a specific, substantial, and credible utility. In the instant case, the credibility of the data indicating that the *Evi27* is a member of the IL-17R family is not being refuted, but rather the fact that the function of the *Evi27* gene would have the same function as that already prescribed to the other IL-17R family members. Assignment of a novel protein to a family of proteins is not sufficient to indicate that the novel protein would have the same function, and as such would have the same specific utility. Applicant states that the modulation of the instant invention would be envisioned by the skilled

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artisan as an obvious utility for the broad treatment of cancer and autoimmune diseases, however, the specification has not taught which of these diseases the instantly claimed gene would be involved, how modulation is to take place and how if modulated the gene/protein would be effected. Because there is a lack of a specific and substantial utility, the instant claims do not comply with the utility requirements of 35 USC 101.

6. The rejection of claims 1-8 under 35 U.S.C. 112, first paragraph is maintained for the reasons of record. Specifically, since the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
October 21, 2003


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600